

**Post Market Surveillance Review to 31<sup>st</sup> December 2020**

## **4310003 Flowsensor SpiroTrue H. Box of 6**

Bluepoint Medical ref.: **103013200**

First sold: **8<sup>th</sup> May 2009**

Total sales to date: **6,790 boxes, 49 different customers across 29 countries**

Total failures: **2 boxes**

Total returns: **2 packs – failed calibration on Hamilton G5 ventilator, reported then returned to Viamed for credit 10/12/2009. Sensors supplied to Bluepoint Medical for evaluation 29/12/2009**

Customer: **Royal Sussex County Hospital SRS61983**

Total customer failures: **0.03%**



**For the period from 30<sup>th</sup> December 2009 to 31<sup>st</sup> December 2020, there has not been any new reported failures or failures that refer to the claims listed above.**

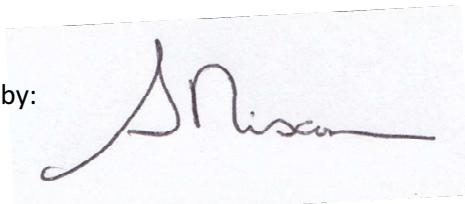
The design, functionality and reliability of the sensor is very good. We do include feedback forms within each box of sensors for end users to be able to easily report possible issues and/or for confirming compatibility. Unfortunately, we get very few feedback forms returned as the customers are happy with the sensors and have nothing to report.

Applications:

<b>Manufacturer</b>	<b>Description</b>	
Biometric Cables	910246002	Flow Sensor
Biometric Cables	FS2	Flow Sensor
Draeger	Oxilog 2000 Plus (if disposable circuits used)	Ventilator
Draeger	Oxilog 3000 (if disposable circuits used)	Ventilator
Draeger	Oxilog 3000 Plus (if disposable circuits used)	Ventilator
Draeger	VentStar	Ventilator
Hamilton Medical	155362	Flow Sensor
Hamilton Medical	279331	Flow Sensor
Hamilton Medical	53120	Flow Sensor
Hamilton Medical	Amadeus	Ventilator
Hamilton Medical	C1	Ventilator
Hamilton Medical	C2	Ventilator
Hamilton Medical	G5	Ventilator
Hamilton Medical	Galileo	Ventilator
Hamilton Medical	H72	Ventilator

Hamilton Medical	H7200	Ventilator
Hamilton Medical	H7400 AccuTach	Flow Sensor
Hamilton Medical	MR1	Ventilator
Hamilton Medical	Raphael	Ventilator
Hamilton Medical	S1	Ventilator
Hamilton Medical	T1	Ventilator
Hamilton Medical	Veolar	Ventilator
Hamilton Medical	VR-1	Ventilator
Lub Dub Medical	OX-2530	Flow Sensor
Med-Shopping	MAC-VTA-OTH-FSH7200	Flow Sensor
Viamed	3030131005	Flow Sensor
Viamed	1030132000	Flow Sensor
Viamed	Flowsensor H	Flow Sensor
Viamed	SpiroTrue H	Flow Sensor

Reviewed by:



Steve Nixon  
Director – Viamed Ltd.

Date: 5<sup>th</sup> February 2021